



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
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JUN 10 2003

WYETH  
PATENT LAW GROUP  
FIVE GIRALDA FARMS  
MADISON, NJ 07940

Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,626,538

The change of address, filed May 23, 2003, is noted. A change in address in the patented file does not result in a change of address to the patent term extension application since papers directed to the patent file (as in a paper related to a change of an address to customer number) are neither matched with the patent term extension file, nor directed to the Food and Drug Administration. Moreover, when the correspondence address is designated as a customer number, the FDA would not be notified when the address associated with a customer number changes. As a result, any earlier change of address to the customer number did not, and would not, change the address for the above-identified patent term extension application. See also Manual of Patent Examining Procedure, Section 2753 which states:

If the address is changed after filing the application for patent term extension, the change of address should be sent to Box Patent Extension, since changing the address for the patent file will not cause the address for the patent term extension application to also be changed.

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,626,538 for a period of 1,810 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: <http://www.fda.gov/cder/orange/patdecl.pdf>.

As to the "Comment on the FDA Regulatory Review Period Calculation," filed March 21, 2003, the undersigned contacted the Food and Drug Administration by telephone and confirmed that the FDA's records do reflect an IND effective date of May 2, 1991, although not, as stated in the determination, because that date is 30 days after the received by FDA of the IND.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: David T. Read  
Health Assessment Policy Staff  
Acting Director Health Assessment Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

RE: Sonata  
FDA Docket No.: 00E-1234

# UNITED STATES PATENT AND TRADEMARK OFFICE

## (12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 4,626,538  
(45) ISSUED : December 2, 1986  
(75) INVENTOR : John P. Dusza, et al.  
(73) PATENT OWNER : Wyeth  
(95) PRODUCT : Sonata® (zaleplon)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 4,626,538 based upon the regulatory review of the product Sonata® (zaleplon) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 1,810 days

from June 23, 2003, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 4th day of June 2003.

  
JAMES E. ROGAN  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office